Exhibit 1

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DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

Departmental Appeals Board, MS 6127
Medicare Appeals Council
330 Independence Avenue
Cohen Building, Room G-644
Washington, DC 20201
(202)565-0100/Toll Free:1-866-365-8204

FEB 24 2016

ALJ Appeal Numbers: 1-2911738005 and 1-2838936764
Docket Number: M-15-4332

Jonathan A. Bloom
120 Nicklaus Circle
South Burlington, VT 05403

NOTICE OF DECISION OF MEDICARE APPEALS COUNCIL

What This Notice Means

Enclosed is a copy of the decision of the Medicare Appeals Council. If you have any questions, you may contact the Centers for Medicare & Medicaid Services regional office or the local Medicare contractor.

Your Right to Court Review

If you desire court review of the Council's decision and the amount in controversy is $1,500 or more, you may commence a civil action by filing a complaint in the United States District Court for the judicial district in which you reside or have your principal place of business. *See* § 1869(b) of the Social Security Act, 42 U.S.C. § 1395ff(b). The complaint must be filed within sixty days after the date this letter is received. 42 C.F.R. § 405.1130. It will be presumed that this letter is received within five days after the date shown above unless a reasonable showing to the contrary is made. 42 C.F.R. § 405.1136(c)(2).

If you cannot file your complaint within sixty days, you may ask the Council to extend the time in which you may begin a civil action. However, the Council will only extend the time if you provide a good reason for not meeting the deadline. Your reason must be set forth clearly in your request. 42 C.F.R. § 405.1134.

If a civil action is commenced, the complaint should name the Secretary of Health and Human Services as the defendant and should include the Council's docket number and ALJ appeal numbers shown at the top of this notice. 42 C.F.R. § 405.1136(d). The Secretary must be served by sending a copy of the summons and complaint by registered or certified mail to the General Counsel, Department of Health and Human Services, 200 Independence Avenue, S.W., Washington, D.C. 20201. In addition, you must serve the United States Attorney for the district in which you file your complaint and the Attorney General of the United States. *See* rules 4(c) and (i) of the Federal Rules of Civil Procedure and 45 C.F.R. § 4.1.

Enclosure

cc: Vermont Legal Aid, Inc.
Q2A AdQIC Records Management

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL
Docket Number: M-15-4332

In the case of	**Claim for**
J.B. (Appellant)	Supplementary Medical Insurance Benefits (Part B)
Jonathan A. Bloom (Beneficiary)	XXX-XX-9397A (HIC Number)
NHIC, Corp. (Contractor)	1-2911738005 and 1-2838936764 (ALJ Appeal Numbers)

Two Administrative Law Judge (ALJ) decisions were issued on March 31, 2015 and April 8, 2015. In the March 31, 2015 decision (ALJ No. 1-2911738005), the ALJ found that Medicare does not cover continuous glucose monitoring sensors (HCPCS code[1] A9276) and transmitter (A9277) furnished to the appellant-beneficiary (beneficiary) on June 18, 2014 and June 27, 2014, respectively. In the April 8, 2015 decision (ALJ No. 1-2838936764), the ALJ found that Medicare does not cover continuous glucose monitoring sensors (HCPCS code A9276) furnished to the beneficiary on March 19, 2014. The beneficiary has asked the Medicare Appeals Council (Council) to review both ALJ decisions. After the beneficiary submitted his requests for review, the beneficiary appointed an attorney to act as his representative in this appeal.

The Council reviews the ALJ's decisions *de novo*. 42 C.F.R. § 405.1108(a).

As set forth below, the Council finds no basis for changing the ALJ decisions. The Council therefore adopts the ALJ decisions.

[1] The Centers for Medicare & Medicaid Services (CMS) developed the Healthcare Common Procedure Coding System (HCPCS) to establish "uniform national definitions of services, codes to represent services, and payment modifiers to the codes." 42 C.F.R. § 414.40(a).

CASE RECORD

The Council admits the following into the record:

Exh. MAC-1	The appellant's request for review for ALJ No. 1-2911738005
Exh. MAC-2	The appellant's request for review for ALJ No. 1-2838936764
Exh. MAC-3	The appellant's requests for escalation and appointment of representative
Exh. MAC-4	The appellant's requests to withdraw its escalation request and request for extension of time to file a civil action for the Council's decision in Docket Number M-15-1505
Exh. MAC-5	The appellant's request for extending the deadline for filing its requests for review

BACKGROUND

The record indicates that the beneficiary is a type 1, insulin-dependent, diabetic, who has been using a continuous glucose monitor (CGM) since 2006 to manage his diabetes and hypoglycemia. *See, e.g.*, Claim File for ALJ No. 1-2838936764, Exh. 7 at 4-5. In the past, the beneficiary has appealed coverage denials for disposable sensors used with his CGM at the ALJ level for various dates of service. *See, e.g.*, Claim File for ALJ No. 1-2838936764, Record at 00964-01027.[2] Most recently, the Council accepted a CMS referral for own motion review to review an ALJ's decision concerning coverage for CGM sensors furnished to the beneficiary on August 6, 2014. *See* Docket Number M-15-1505 (Nov. 13, 2015). In that case, we reversed the ALJ's decision and found that, because CGMs do not fall within the durable medical equipment (DME) benefit category, supplies such as sensors for CGMs are also non-covered. *See id.*

The instant case now before the Council concerns claims for disposable CGM sensors, HCPCS code A9276-GX[3], furnished to the beneficiary on March 19, 2014 and June 18, 2014, and a CGM transmitter, HCPCS code A9277, furnished to the beneficiary on June 27, 2014. The contractor and the Qualified Independent

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[2] In the claim file for ALJ No. 1-2838936764, the ALJ did not mark some of the pages into exhibits. To cite to these unmarked pages, the Council cites to the Bates stamp page numbering at the lower left hand corner of each page.

[3] The modifier "GX" indicates: "Notice of liability issued, voluntary under payer policy)." HCPCS and CPT Codebook (2014).

Contractor (QIC) denied coverage and held the beneficiary financially responsible for the non-covered charges. *See, e.g.*, Claim File for ALJ No. 1-2838936764, Exh. 1 at 1; Exh. 2 at 1-2; Exh. 4 at 1-4.

Following ALJ hearings for these claims, an ALJ rendered an unfavorable decision on March 31, 2015 (ALJ No. 1-2911738005) for the disposable CGM sensors furnished on June 18, 2014 and for the CGM transmitter furnished on June 27, 2014. Another ALJ rendered an unfavorable decision on April 8, 2015 (ALJ No. 1-2838936764) for disposable CGM sensors furnished on March 19, 2014.

In the March 31, 2015 decision, the ALJ discussed the definition of DME found in 42 C.F.R. § 414.202 and the Medicare Benefit Policy Manual (MBPM) (IOM Pub. 100-02), Ch. 15, § 110.1. The ALJ also discussed the guidelines in the Local Coverage Determination (LCD) L11530 and the related Policy Article A33614. The ALJ found that Policy Article A33614 excludes coverage for CGM items billed under HCPCS codes A9276 through A9278 on the grounds that they are precautionary and therefore non-covered under the DME benefit. The ALJ concluded that the sensors and transmitter furnished to the beneficiary are not covered by Medicare because they did not meet the definition of DME under the applicable guidelines. The ALJ also concluded that the beneficiary was financially responsible for the non-covered charges.

In the April 8, 2015 decision, the ALJ also discussed the guidelines in the LCD L11530 and the related Policy Article A33614. The ALJ concluded that, because Policy Article A33614 specifically excludes coverage for CGMs under the DME benefit as they are considered precautionary, the sensors used with the non-covered CGM are also not covered by Medicare. The ALJ also concluded that the beneficiary was financially responsible for the non-covered charges.

Before the Council, the beneficiary requests the Council to reconsider the ALJ decisions. The appellant states that he has appealed similar denials to the ALJ and has received four fully favorable ALJ decisions since 2010. The appellant also states that he has attached three letters from his physicians supporting his need for CGMs. The appellant further states that he has severe unrecognizable hypoglycemia and has had several instances of hypoglycemic awareness that resulted in emergency ambulance calls. Exhs. MAC-1 and MAC-2.

By letters dated December 29, 2015, the beneficiary requested an escalation to the federal district court under 42 C.F.R. § 405.1132. Exh. MAC-3. The beneficiary subsequently withdrew its requests for escalation and requested the Council to extend the deadline for filing its requests for review for good cause. Exh. MAC-4. The beneficiary also requested the Council to extend the time to file a civil action for the Council's decision in Docket Number M-15-1505. *Id.*

PRELIMINARY ISSUES

As a preliminary matter, the beneficiary requests an extension of time to file a civil action for the Council's decision in Docket Number M-15-1505. In a letter sent by facsimile dated January 15, 2016, the Council granted the beneficiary's request, giving the beneficiary 65 days from the date of the letter to file a civil action.

The beneficiary also requests the Council to extend the deadline for filing its requests for review in the instant case. Exh. MAC-5. The requests for review in the instant case were filed on June 15, 2015, but the deadline for filing the requests for review for the March 31, 2015, and April 8, 2015 ALJ decisions were June 4, 2015, and June 12, 2015, respectively. *See generally* 42 C.F.R. § 405.1102. The regulations provide that the Council will dismiss a request for review where the appellant fails to file the request within the stated period of time and the Council has not extended the time period for filing. *See* 42 C.F.R. § 405.1114. The time period will be extended if good cause is shown for missing the deadline. *See* 42 C.F.R. § 405.1102(b). Examples of circumstances when good cause may be found to exist include, but are not limited to, the following situations: serious illness, destruction by fire of important records, misinformation regarding when and how to appeal, failure to receive the decision, or the appeal being sent to the wrong government address in good faith. *See* 42 C.F.R. § 405.942(b)(3), *incorporated by reference at* 42 C.F.R. § 405.1102(b)(3).

The beneficiary asserts that there is good cause for extending the filing deadline. Exh. MAC-5. In his affidavit, the beneficiary states that he had trouble keeping track of the deadline for several reasons: (1) he had a major sinus surgery in May 2015 and was in recovery, (2) he had a possible carcinoid tumor in his mesentery and so he had multiple follow-up doctor

visits and tests in May and June 2015, (3) he had multiple Medicare appeals at different levels in the appeals process, and (4) he was seeking representation from the Legal Aid clinic, before he undertook this appeal on his own. Exh. MAC-5. Based on the evidence, the Council finds that there is good cause for extending the deadline for filing the requests for review. The Council therefore finds that the beneficiary's requests for review were timely filed pursuant to 42 C.F.R. § 405.1102. We proceed to address the merits of the beneficiary's claims on appeal below.

DISCUSSION

The Council has carefully considered the administrative record, including the ALJ's decisions and the beneficiary's exceptions. For the reasons explained below, we agree with the ALJ that the CGM transmitter and disposable sensors at issue are non-covered under the DME benefit category.

We note at the outset that neither ALJ decisions nor Council decisions are precedential or binding on subsequent Council decisions. 70 Fed. Reg. 11420, 11449 (Mar. 8, 2005). Therefore, although the Council has issued a decision in M-15-1505 regarding coverage for CGM sensors furnished to the beneficiary on a different date of service and although the beneficiary has received favorable ALJ decisions for CGM sensors in some cases, prior Council and ALJ decisions regarding similar services are not dispositive of the coverage issues in the instant case.

Medicare Coverage of CGMs

Medicare is a defined benefits program. Section 1832(a) of the Act provides that benefits under Medicare Part B include "medical and other health services." Section 1861(s)(6) of the Act defines "medical and other health services" as including DME. Section 1861(n) of the Act lists certain items that are classified as DME. That list includes "blood-testing strips and blood glucose monitors for individuals with diabetes" but does not specifically mention CGMs. By its own terms, however, section 1861(n) is not an exhaustive list of those items that qualify as DME.

The regulation at 42 C.F.R. § 414.202 defines DME as equipment that can withstand repeated use; is primarily and customarily used to serve a medical purpose; generally is not useful to an

individual in the absence of an illness or injury; and is appropriate for use in the home. Medicare covers DME if it: (1) meets the definition of DME; (2) is medically "reasonable and necessary"; and (3) the equipment is used in the beneficiary's home. MBPM, Ch. 15, § 110. Therefore, the first step in the analysis requires consideration of whether an item or device meets the definition of DME. Only if the device meets the definition of DME, does the analysis then proceed to determine whether the device is medically reasonable and necessary for the beneficiary in a particular case.

To determine whether CGMs are covered under Medicare, we must also consider whether CMS has issued an applicable NCD specifically addressing CGMs. "An NCD is a determination by the Secretary of whether a particular item or service is covered nationally under Medicare." 42 C.F.R. § 405.1060(a). "NCDs generally outline the conditions for which an item or service is considered to be covered (or not covered) under § 1862(a)(1) of the Act or other applicable provisions of the Act." Medicare Program Integrity Manual (MPIM), CMS Pub. 100-08, Ch. 13, § 13.1.1. NCDs are binding on all contractors, ALJs, and the Council. 42 C.F.R. § 405.1060(a)(4).

CMS has issued NCD 280.1, "Durable Medical Equipment Reference List," which was "designed to facilitate the [contractor's] processing of DME claims." NCD 280.1. This NCD includes a list of items that CMS has determined are covered under Medicare's DME benefit. NCD 280.1. The NCD states that if the contractor receives a claim for equipment "which does not appear to fall logically into any of the generic categories listed," the contractor must determine whether the equipment is covered under the DME benefit. *Id.* The DME reference list indicates that Medicare covers "Blood Glucose Monitors," if a beneficiary meets certain conditions, and cross-references NCD section 40.2. *Id.* The list does not include CGMs specifically. *Id.*

As referenced in NCD 280.1, we turn to NCD 40.2 for Home Blood Glucose Monitors, which classifies home blood glucose monitors as DME and addresses the circumstances under which they are considered medically reasonable and necessary. This NCD states that "[b]lood glucose monitors are meter devices that read color changes produced on specially treated reagent strips by glucose concentrations in the patient's blood." NCD 40.2. It further describes how blood glucose monitors are used: "The patient, using a disposable sterile lancet, draws a drop of blood, places it on a reagent strip and, following instructions which may vary

with the device used, inserts it into the device to obtain a reading." *Id.* However, NCD 40.2 does not specifically address CGMs, which do not measure glucose in the blood but rather in the interstitial fluid. *See* Joint DME contractor Publication, available at: https://www.dmepdac.com/resources/articles/2014/08_13_14.html (last visited Feb. 22, 2016). *See also* the manufacturer supplier's website, http://www.medtronicdiabetes.com/products/continuous-glucose-monitoring (stating that CGMs measure glucose levels in tissue fluid) (last visited Feb. 22, 2016).[4] Accordingly, because CGMs are not blood glucose monitors, we conclude that NCD 40.2 is not directly applicable in the case of CGMs and, therefore, there is no applicable NCD that specifically addresses Medicare coverage of CGMs.

We next must determine whether the contractor has issued a relevant LCD and/or related policy article that was in effect on the date of service at issue. "An LCD is a decision by a Medicare administrative contractor . . . whether to cover a particular item or service on a [contractor]-wide basis in accordance with Section 1862(a)(1)(A) of the [Act] (i.e., a determination as to whether the item or service is reasonable and necessary)." MPIM, Ch. 13, § 13.1.3. Information that is not related to reasonableness and necessity coverage criteria is published through an article. *Id.* The Council, like the ALJ, is not bound by program guidance, including specifically "LCDs, LMRPS, or . . . program memoranda and manual instructions," but we must give these policies substantial deference if they are applicable in a given case. 42 C.F.R. § 405.1062(a). If an ALJ or the Council declines to follow this guidance, the decision must explain the basis for his departure. 42 C.F.R. § 405.1062(b). Historically we have also given substantial deference to policy articles.

In the instant case, the contractor that reviewed the beneficiary's claims had published LCD L11530 and related Policy Article A33614, both entitled "Glucose Monitors." Versions of each document were in effect on the date of service. The LCD identifies the criteria a beneficiary must meet to be eligible for Medicare-covered home blood glucose monitors. LCD L11530. The LCD includes a list of relevant HCPCS codes, which includes the code at issue in this case. *Id.* However, the LCD specifies

[4] We have taken judicial notice of the supplier's website in this case as it is in the public domain. The supplier accepted assignment and is a party. *See* 42 C.F.R. § 405.906; Claim File for ALJ 1-2911738005, Exh. 4 at 4, 6; Claim File for 1-2838936764, Exh. 1 at 1.

that "[t]he appearance of a code in this section does not necessarily indicate coverage." *Id.*

Under the "Medical Record Information" section, the LCD explains:

> The **Coverage Indications, Limitations and/or Medical Necessity** section of this LCD contains numerous reasonable and necessary (R&N) requirements. The **Non-Medical Necessity Coverage and Payment Rules** section of the related Policy Article contains numerous non-reasonable and necessary, benefit category and statutory requirements that must be met in order for payment to be justified.

LCD L11530 (underlining added). Policy Article A33614 lists several items that are non-covered because they do not meet the definition of the DME benefit category. For example, glucose monitors not designed for use in the home will be denied as statutorily non-covered. Policy Article A33614. Similarly, disposable home blood glucose monitors are not covered. *Id.* Finally, of particular importance in this case, the Policy Article states that "[CGMs] (A9276-A9278) are considered precautionary and therefore non-covered under the DME benefit." *Id.*

Here, the claims at issue concerned disposable CGM sensors with HCPCS code A9277 and CGM transmitter with HCPCS code A9277. The applicable Policy Article A33614 makes clear that those CGM items do not meet the definition of DME because they are precautionary. While the term "precautionary" is not a statutorily defined term, it refers to the requirement that DME must itself serve a medical purpose. Where the beneficiary must still use another device to accomplish the medical purpose at issue, it is essentially used as an additional precaution, but not for a primary medical purpose.[5]

As the beneficiary testified during one of the ALJ hearing, although CGMs may help spot glucose trends, the beneficiary would still need to monitor his blood glucose levels using a finger stick. ALJ No. 1-2838936764, Hearing Recording. In

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[5] The categorization of spare tanks of oxygen and preset portable oxygen units as "precautionary" in section 280.1 of chapter 1 of the NCD Manual is similar to this case since a beneficiary using spare tanks or preset portable oxygen units would still have to rely on the primary equipment available, such as an adjustable portable oxygen system or primary oxygen tank. *See* NCD § 280.1.

addition, the manufacturer supplier's website, of which we have taken judicial notice, indicates that blood glucose testing is required to calibrate the CGM at least once every 12 hours, though the supplier recommends three-to-four blood tests for "optimal glucose sensor accuracy." The website further indicates that "[i]t is still required to check blood glucose levels with a fingerstick before therapy adjustment." Therefore, since the CGM does not substitute for the existing means of controlling insulin usage, or measure blood glucose directly, we conclude that it merely provides an added precaution and does not itself serve a primary medical purpose. Accordingly, we find no basis to depart from the applicable program guidance, which provides that CGMs assigned with HCPCS codes A9276 through A9278 (such as the sensors and transmitter at issue) do not meet the definition of DME because they are precautionary.

As discussed above, Medicare is a defined benefit program. Therefore, the items at issue must first fall within the DME benefit category by meeting the DME definition before we determine whether the items are medically reasonable and necessary for the beneficiary in a particular case. While we do not question the benefit that the beneficiary derives from the use of CGMs, the beneficiary's personal use of and need for CGMs and it supplies do not factor into the determination of whether these items itself fall within the statutory DME benefit category. Because CGMs do not meet the definition of DME for coverage under that statutory category, we have no need to address the issue of whether a CGM may be medically reasonable and necessary for this beneficiary. We conclude that CGMs (and thus, the sensors and transmitter at issue) do not fall within a defined Medicare benefit category.

Liability

Regarding financial responsibility, the ALJs found that the beneficiary was financially responsible for the non-covered charges. We agree. Under section 1879 of the Act, Medicare may limit the liability of a beneficiary, provider, or supplies for the non-covered costs of items where the coverage denial was based on a finding that the items were not medically reasonable and necessary pursuant to section 1862(a)(1)(A) of the Act. However, here, as we have explained, the analysis does not concern whether the CGM transmitter and sensors are medically reasonable and necessary but rather whether they meet the definition of DME and thus, whether they fall under that

statutory benefit category, which we find that they do not. Therefore, the limitation on liability provisions of section 1879 do not apply in this case and the beneficiary is financially responsible for the non-covered items. *See* Medicare Claims Processing Manual (MCPM), CMS Pub. 100-04, Ch. 30, § 20.2.2 (Section 1879 does not apply to "technical denials," such as in cases where an item does not meet the definition of DME.).

DECISION

For the foregoing reasons, the Council adopts the ALJ decisions in the instant case. We agree with the ALJs that Medicare does not cover a CGM transmitter furnished to the beneficiary on June 27, 2014, and CGM sensors furnished to the beneficiary on March 19, 2014 and June 18, 2014. CGMs do not fall within the DME benefit category, and, therefore, supplies for such devices are also non-covered. The beneficiary remains financially responsible for the non-covered items.

MEDICARE APPEALS COUNCIL

Clausen J. Krzywicki
Administrative Appeals Judge

Date: FEB 24 2016